

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 1. RULES AND THE RULEMAKING PROCESS

CHAPTER 6. GOVERNOR'S REGULATORY REVIEW COUNCIL

PREAMBLE

1. **Sections Affected:**

<u>Rulemaking Action</u>	
R1-6-101	Amend
R1-6-102	Amend
R1-6-103	Amend
R1-6-104	Amend
R1-6-105	Amend
R1-6-107	New Section
R1-6-108	Amend
Article 3	New Article
R1-6-301	New Section
Article 4	New Article
R1-6-401	New Section
2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. § 41-1051(E), provides the Council with general authority to adopt these rules.

Implementing statutes: A.R.S. § 41-1051 provides specific authority for R1-6-101.
A.R.S. §§ 41-1052 and 41-1056 provide specific authority for R1-6-102.
A.R.S. §§ 41-1052 and 41-1056 provide specific authority for R1-6-103.
A.R.S. § 41-1052(B) and (C) provide specific authority for R1-6-104.
A.R.S. § 41-1052(B) and (C) provide specific authority for R1-6-105.
A.R.S. § 41-1052(E) provides specific authority for R1-6-107.
A.R.S. § 41-1056 provides specific authority for R1-6-108.
A.R.S. § 41-1033 provides specific authority for R1-6-301.
A.R.S. § 41-1056.01 provides specific authority for R1-6-401.
3. **The effective date of the rules if different from the date the rules are filed with the Secretary of State:**

April 3, 1996.
4. **List of all previous notices appearing in the Register addressing the final rule:**

Notice of Rulemaking Docket Opening:
1 A.A.R. 1781, October 6, 1995

Notice of Rulemaking Docket Opening:
1 A.A.R. 2605, December 1, 1995

Notice of Proposed Rulemaking:
1 A.A.R. 2524, December 1, 1995
5. **Name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Robert Dalager, Administrator
Address:	Governor's Regulatory Review Council 1400 West Washington, Suite 270 Phoenix, Arizona 85007
Telephone:	(602) 542-2058
Fax:	(602) 542-1486

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6. An explanation of the rules, including the agency's reasons for initiating the rules:

The rules set forth requirements for scheduling Council meetings, establishing filing deadlines, submitting rule packages, approving and returning rules, appealing a decision regarding an agency practice or substantive policy statement, and appealing a decision regarding an economic, small business, and consumer impact statement.

R1-6-101: The amendments set scheduling for Council meetings on a calendar-year basis rather than a fiscal-year basis. Also, consistent with the Council's new statutory responsibilities, language is added to allow scheduling of special meetings for appeals of economic, small business, and consumer impact statements and substantive policy statements.

R1-6-102: The amendments set scheduling for submission deadlines on a calendar-year basis rather than a fiscal-year basis. A citation error is also corrected.

R1-6-103: The amendments reflect accurately the type, number, and order of documents to be submitted to the Council for adopted rules. The result is that fewer copies of documents will be required.

R1-6-104: The amendments indicate that the Council will submit agency certificates and receipts when the Council submits an approved rule package to the Secretary of State. References to approved rules being filed by the agency with the Secretary of State are deleted.

R1-6-105: The amendments make the rule consistent with A.R.S. § 41-1052(B). The statute makes resubmission of a rule permissive.

R1-6-107: This new rule deals with submission of written comments and visual aids to the Council and the affected agency before a meeting.

R1-6-108: The amendment reflects accurately the type, number, and order of documents to be submitted to the Council for 5-year-review reports. The result is that fewer documents will be required.

The Council is required by A.R.S. § 41-1033(B) to review appeals of an agency's final decision whether to adopt as a rule an existing agency practice or substantive policy statement that any petitioning person alleges constitutes a rule. R1-6-301 provides guidelines for filing the appeal and notification procedures preceding and following a Council meeting.

The Council is required by A.R.S. § 41-1056.01(D) to review appeals of an agency's economic, small business, and consumer impact statement objected to by a person pursuant to A.R.S. § 41-1056.01. R1-6-401 provides guidelines for filing the appeal and notification procedures preceding and following a Council meeting.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

8. The summary of the economic, small business, and consumer impact:

A. Adopted rulemaking

R1-6-101 requires change to set scheduling for Council meetings on a calendar-year basis, rather than a fiscal-year basis. Also, language is being added to allow scheduling of special meetings for appeals of economic, small business, and consumer impact statements and appeals of substantive policy statements. R1-6-102 requires change to set scheduling for submission deadlines on a calendar year basis, rather than a fiscal year basis. A citation error is also being corrected. R1-6-103 requires change to accurately reflect the type, number, and order of documents to be submitted to the Council. The result is that fewer documents will be required. R1-6-104 needs to include submission of agency certificates and agency receipts. References to approved rules being filed by the agency with the Secretary of State are being deleted. R1-6-105 needs to be changed to be consistent with A.R.S. § 41-1052(B). The statute makes permissive the resubmission of a rule. R1-6-107 is a new Section. This rule deals with submission of written comments and visual aids to the Council prior to a meeting. R1-6-108 requires change to accurately reflect the type, number, and order of documents to be submitted to the Council for 5-year-review reports. The result is that fewer documents will be required.

The Council is required by A.R.S. § 41-1033(B) to review appeals of an agency's final decision whether to adopt as a rule an existing agency practice or substantive policy statement that any petitioning person alleges to constitute a rule. R1-6-301 provides guidelines for filing the appeal and for notification procedures preceding and following a Council meeting. The Council is required by A.R.S. § 41-1056.01(E) to review appeals of an agency's final decision whether to adopt, amend, or repeal a rule objected to by a person pursuant to A.R.S. § 41-1056.01. R1-6-401 provides guidelines for filing the appeal and for notification procedures preceding and following a Council meeting.

B. Information contained in this report

The changes in the GRRC rules make the rules easier to understand. The rules provide order for agency submittals and group the submissions in a standard format. The rules reduce the overall number of copies required for rule package submissions. R1-6-301 and R1-6-401 are procedural rule changes required by statute.

9. A description of the changes between the proposed rules including supplemental notices, and the final rules:

General punctuation changes were made as needed.

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R1-6-101

Subsection (A): Insert "A.R.S. § 38-431, et. seq." after the reference to the Open Meeting Law.

Subsection (A): Delete "at least 10 calendar days before a regular meeting."

Subsection (B): Insert "A.R.S. § 38-431, et. seq." after the reference to the Open Meeting Law.

R1-6-102

Subsection 2. Omit reference to ~~(A)~~

R1-6-103

Subsection (A): After "office" add "the following documents formatted as required by the rules of the Secretary of State."

Subsection (A)(1)(a): Change "agency director" to "agency head."

Subsection (A)(1)(a)(ii): Strike "procedures followed for adopting the rule including the."

Subsection (A)(1)(b): Insert "A.A.C." between "by" and "R1-1-601."

Subsections (A)(1)(g) and (h): Omit (g) and (h) and relabel remaining subsections.

Subsection (A)(1)(a)(iii): Omit the "and" at the end of the subsection.

Subsection (A)(1)(a)(iv): Change subsection (iv) to subsection (v). Add a new subsection (iv), as follows;

"iv. If applicable, a statement that the rulemaking relates to a 5-year-review report and the date the report was accepted by the Council; and"

Subsection (A)(2)(a): Insert "proposed" between "the" and "rule."

Subsection (A)(2)(a): Add "and" after the semi-colon.

Subsection (A)(2)(b): Insert "Materials" before "Incorporations." Change "Incorporations" to "incorporated." Change semi-colon to a period.

Subsection (B): After the last "Council" add "the following documents formatted as required by the rules of the Secretary of State."

Subsection (B)(2)(a): Insert "A.A.C." between "by" and "R1-1-6-105(B)."

Subsection (B)(3): Omit the comma after "receipt."

Subsection (B)(3): Insert "A.A.C." between "by" and "R1-1-106."

Subsection (C): After "office" add "the following documents formatted as required by the rules of the Secretary of State."

Subsection (C)(1)(a): Strike "The" at the beginning of the sentence. Change the period at the end of the sentence to a semi-colon.

Subsection (C)(2)(a)(i): Omit "Final." Change "R1-1-601" to "R1-1-801." Insert "A.A.C." between "by" and "R1-1-801."

Subsection (D): After the last "Council" add "the following documents formatted as required by the rules of the Secretary of State."

Subsection (D)(1): Change the period at the end of the sentence to a semi-colon.

Subsection (D)(2)(a): Insert "A.A.C." between "by" and "R1-1-105(B)."

Subsection (D)(2)(c): Omit the "the" between "in" and "subsections."

Subsection (D)(3): Omit the comma after "receipt."

Subsection (D)(3): Insert "A.A.C." between "by" and "R1-1-106."

R1-6-104

Subsection (A): Delete "and" before "economic."

Subsection (B): Eliminate the strike from "preamble." Insert a comma between "business" and "and."

Subsection (B)(1): Insert a comma between "business" and "and."

R1-6-105

Initial paragraph: Eliminate the strike from "preamble." Omit "~~(C)~~" and the underline from "(B)."

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R1-6-107

Subsections (A) and (B): In both subsections, insert "head" after "agency" and insert "and the office of the agency head" between "office" and "at."

Subsection (B): At the beginning of the 2nd sentence add "A person making oral comments shall submit". Omit "shall be received in". Insert "to" between "aids" and "the". Omit "any" between "of" and "visual."

Subsection (C): Omit "or matter."

Add a new subsection (D), as follows:

"D. The Chair may permit a person to submit written comments within the scope of A.R.S. § 41-1052(C) or visual aids if the person establishes good cause for not complying with the document and time requirements in subsections (A) or (B).

R1-6-108

Subsection (A)(4): Add ", and a listing of the statutes or rules used in determining the consistency" to the end of the subsection.

Subsection (A)(8): Strike the "and" at the end of the subsection.

Subsection (A)(10): Strike "will" and replace with "anticipates." Change "open" to "opening." After "docket" add "and submitting the rules to the Council".

Subsection (B): Insert "is" before "identical."

Subsection (C): Omit subsection (3). Omit the "and" at the end of subsection (2) and change the semi-colon to a period. Add "and" to the end of subsection (1) and change the semi-colon to a comma.

R1-6-301

Subsection (A)(2): Omit "If submitted to the agency by the person filing the appeal, a copy of." Capitalize "The."

Add a new subsection (A)(3), as follows:

"(A)(3) The agency's written decision to each petition submitted to the agency requesting a review of the agency's existing practice or substantive policy statement being appealed."

Subsections (B) and (C): Change "B" to "C" and "C" to "B."

Subsection (B): Insert "head" between "agency" and "of."

Subsection (B): Change the 1st "notification" to "receipt."

Subsection (B): Change "subsection (B)" to "subsection (C)."

Subsection (C)(4): Change "response" to "decision."

Subsection (D): Insert "head" between "agency" and "stating." Omit the 1st "the."

Subsection (E): Omit "written" from between "a" and "letter."

Subsection (E): Insert "the" between "to" and "affected."

R1-6-401

Subsection (A)(1)(e): Insert "significantly" between "impact" and "exceeded." Change the 1st and 2nd "and" to "or."

Subsection (A)(3): Insert "set forth" between "reasons" and "under."

Subsections (B) and (C): Change "B" to "C" and "C" to "B."

Subsection (B): Insert "head" between "agency" and "of."

Subsection (B): Change the 1st "notification" to "receipt."

Subsection (B): Change "subsection (B)" to "subsection (C)."

Subsection (C)(1)(c): Insert "If appropriate," before "Reasons." Change "Reasons" to "reasons." Change "and/or" to "and." Insert "; or both" between "rule" and "and" at the end of the subsection.

Subsection (C)(1)(d): Change the period at the end of this subsection to a semi-colon.

Subsection (D): Insert "head" between "agency" and "stating."

Subsection (E): Omit "written" from between "a" and "letter." Change the 3rd "decision" to "action."

None of the changes, which are primarily editorial and designed to make the rules more clear and understandable or to address

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comments received from the public, make the adopted rules substantially different from the proposed rules. All individuals affected by the adopted rules would have understood that the published proposed rules would affect their interests. The subject matter of the adopted rules and the issues determined by the adopted rules are not different from the subject matter and issues involved in the published proposed rules. The effects of the adopted rules do not differ from the effects of the published proposed rules if they had been adopted without these changes.

10. A summary of the principal comments and the agency response to them:

The public was invited to submit written comments about the rules between the date on which the proposed rules were published and January 4, 1996, the date on which the rulemaking record was closed. An oral proceeding at which members of the public could appear and comment about the proposed rules was held on January 2, 1996.

R1-6-101(A)

COMMENT: The Council is now voluntarily submitting its agenda to the Secretary of State for publication in the *Register*. This should be a requirement in order to better safeguard the public's right to know.

EVALUATION: The Secretary of State has no obligation to publish the Council agenda in the *Register*, but has been doing so voluntarily. The Council has no authority to require publication of its agenda. The agenda would need to be submitted to the Secretary of State at least 3 weeks before publication. This would inhibit the ability to change the agenda within that time. It will likely be necessary for the agenda to be changed within a short time prior to a meeting to add an appeal of an agency practice, substantive policy statement, etc., or an agency emergency matter.

RESPONSE: No change.

COMMENT: If the time, date, or location of a meeting is changed, the agenda should be re-noticed by letter or fax to each agency with an agenda item, and to any interested parties.

EVALUATION: The commentor is correct that those interested in the Council meeting should be notified of any changes to time, date, or location. However, common sense dictates such notification and a rule to that effect is not necessary. In addition, a failure by the Council to notify those interested of a change would be a violation of the Open Meeting Law, A.R.S. § 38-431, et. seq.

RESPONSE: No change.

COMMENT: Open Meeting Law is only a nickname for A.R.S. § 38-431, et. seq. The legal citation should be added to this rule.

EVALUATION: The commentor is correct.

RESPONSE: Insert "A.R.S. § 38-431, et. seq." after the reference to the Open Meeting Law.

R1-6-101(B)

COMMENT: Open Meeting Law is only a nickname for A.R.S. § 38-431, et. seq. The legal citation should be added to this rule.

EVALUATION: The commentor is correct.

RESPONSE: Insert "A.R.S. § 38-431, et. seq." after the reference to the Open Meeting Law.

COMMENT: Special meeting notices should be faxed to each agency on the agenda and each person who has requested notice of such meetings.

EVALUATION: A.R.S. § 38-431.02(C) requires notice of an open meeting to be posted at least 24 hours before the meeting. This rule doubles the required notice time.

RESPONSE: No change.

R1-6-102

COMMENT: The proposed rule shows a reference to subsection (A) being stricken, but no subsection (A) appears in the current or proposed rule.

EVALUATION: The commentor is correct.

RESPONSE: Omit the "(A)."

R1-6-103(A)(1)(a)

COMMENT: Not all agencies have a director. "Head of agency" or "chief executive officer of the agency" should be used instead.

EVALUATION: The commentor is correct. Director is a limiting term.

RESPONSE: Change "agency director" to "agency head."

R1-6-103(A)(1)(a)(i) and (ii)

COMMENT: Move subsection (i) after subsection (ii) to follow a chronological order.

EVALUATION: Subsection (i) requires that the close of record date and the adoption date be listed 1st in the cover letter to the Council. For Council and staff review, these 2 dates are the most important and are better listed 1st.

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RESPONSE: No change.

R1-6-103(A)(1)(a)(ii)

COMMENT: What procedures are there other than those listed under subsections (1) through (5)?

EVALUATION: The commentor is correct. All that needs to be listed are those items specified in subsections (1) through (5).

RESPONSE: Strike "procedures followed for adopting the rule including the."

R1-6-103(A)(1)(a)(iii)

COMMENT: This item should be deleted. The use of the term "whether" implies that attaching the definitions is optional, but it is required in subsection (l) [now subsection (i)] of this Section.

EVALUATION: Attaching definitions is required only if there are definitions. The statement required by this subsection is used to determine whether an agency has intentionally attached or not attached definitions rather than inadvertently omitted them.

RESPONSE: No change.

R1-6-103(A)(1)(g) and (h)

COMMENT: The required items are redundant with the contents of the concise explanatory statement.

EVALUATION: The summaries were initially required as an attempt to reduce the amount of paper in a rule package. The commentors correctly compare the requirements of (g) and (h) with the contents of the concise explanatory statement.

RESPONSE: Omit (g) and (h) and relabel the remaining subsections.

R1-6-103(A)(2)(a)

COMMENT: As this provision is referring to proposed rules, the term "proposed" should be added.

EVALUATION: The commentor is correct.

RESPONSE: Insert "proposed" between "the" and "rule."

R1-6-103(A)(2)(b)

COMMENT: It is more clear to say, "Materials incorporated by reference, if any."

EVALUATION: This commentor is correct.

RESPONSE: Insert "Materials" before "Incorporations." Change "Incorporations" to "incorporated."

R1-6-104

COMMENT: The Council should be required to provide the agency with a copy of any changes the Council requires prior to approval of an adopted rule. This would help the Council to specify the exact wording of the changes, be easier on the agency representative at the meeting, and avoid discrepancies.

EVALUATION: Copies of the changes are available at the agency request. Both the recording of the Council meeting and the meeting minutes reflect the exact changes required. In addition, Council staff takes notes at the meetings about the changes. The meeting recording, minutes, and Council staff are available to aid the agency in making complete and correct changes.

RESPONSE: No change.

COMMENT: This rule should be changed to allow Council to approve an adopted rule subject to wording changes provided by the agency.

EVALUATION: This is currently possible. The Council may approve an adopted rule subject to changes, without regard to the source of the suggested changes. However, no matter the source, the Council is directing the change.

RESPONSE: No change.

R1-6-104(B)(1)

COMMENT: This rule should allow an agency to make conforming, but not specifically directed changes, to a rule that has been approved by the Council.

EVALUATION: As the Council is to approve a rule prior to it becoming a final rule, changes after Council approval cannot be made.

RESPONSE: No change.

R1-6-105

COMMENT: Shouldn't "preamble" be deleted from subsections (2), (3), and (4), as well?

EVALUATION: Proposed changes to the Administrative Procedure Act contained in SB 1056 would empower the Council to

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approve or return the rule, preamble, concise explanatory statement, and the economic, small business, and consumer impact statement. There would, therefore, be no need to delete "preamble" from this Section.

RESPONSE: Eliminate the strike from "preamble."

R1-6-107

COMMENT: This Section should include an exemption to the notice provision upon a showing of good cause, so that the Council can waive the rule if appropriate.

EVALUATION: This commentor is correct.

RESPONSE: Add a new subsection (D), as follows:

"D. The Chair may permit a person to submit written comments within the scope of A.R.S. § 41-1052(C) or visual aids if the person establishes good cause for not complying with the document and time requirements in subsection (A) or (B).

R1-6-107(A) and (B)

COMMENT: It would be appropriate to add a requirement that the comments submitted also be received by the agency head at least 6 calendar days before the meeting.

EVALUATION: The commentor is correct.

RESPONSE: In both subsections, insert "head" after "agency" and insert "and the office of the agency head" between "office" and "at."

R1-6-108(A)(6):

COMMENT: The information requested in this subsection is already covered in subsection (A)(3). If a rule is effective in achieving its objective, the question of wisdom is answered. The reverse is also true.

EVALUATION: A.R.S. § 41-1056(A) requires the 5-year-review report to describe the effectiveness of a rule in achieving its objective and the wisdom of a rule. The statute deals with them as separate items. To be consistent with the statute, the rule should also treat them as separate items. Also, it is possible for a rule that is effectively achieving its objective to be unwise if the objective is unwise.

RESPONSE: No change.

COMMENT: Clarify the meaning of "wisdom."

EVALUATION: Wisdom is a term of common meaning. No other definition is necessary.

RESPONSE: No change.

R1-6-108(A)(9)

COMMENT: Specify what to do when there is no prior economic, small business, and consumer impact statement.

EVALUATION: A.R.S. § 41-1056 requires that the 5-year-review report contain a comparison of the actual impact of the rules with the economic impact statement prepared on the adoption of the rules. To specify in rule what to do if there is no prior statement, would be to allow a waiver of the statutory requirements. The Council has no authority to do that.

RESPONSE: No change.

R1-6-108(A)(10)

COMMENT: This subsection should be changed to read: "Course of action the agency anticipates in opening a rulemaking docket, if the agency determines it is necessary to amend, repeal, or adopt a rule."

EVALUATION: This commentor is partially correct in that future dates are best described as anticipated. The influence of many factors inhibits certainty.

RESPONSE: Strike "will" and replace with "anticipates." Change "open" to "opening." After "docket" add "and submitting the rule to the Council."

R1-6-108(B)

COMMENT: Change "shall" to "may" to allow the grouping of information as an option.

EVALUATION: Both Council and staff have limited time in which to review the extensive amount of rules and reports they receive. Grouping of like information greatly aids the efficiency of Council and staff and reduces paperwork.

RESPONSE: No change.

R1-6-108(C)(3)

COMMENT: The requirement of a matrix is redundant and unnecessary work.

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EVALUATION: The commentor is correct.

RESPONSE: Omit subsection (C)(3).

R1-6-301

COMMENT: This rule places new copying burdens on the agencies and the public. The economic, small business, and consumer impact statement needs to address this.

EVALUATION: The commentor is correct that this rule creates a new burden. However, the rules as amended reduce the overall copying burden.

RESPONSE: No rule change, but see the economic, small business, and consumer impact statement.

R1-6-301(A)(2)

COMMENT: The 1st clause of this subsection is baffling and should be deleted. It seems to suggest that a person can appeal an agency's final decision on someone else's petition.

EVALUATION: A.R.S. § 41-1033(A) refers to the person filing the petition as the petitioner. A.R.S. § 41-1033(B) then says, "A person may appeal to the council..." (underline added.) Petitioner is not used. The conclusion is that the legislature intended a distinction and that standing to appeal is not limited to the petitioner.

RESPONSE: For reasons other than those in the comment, omit "If submitted to the agency by the person filing the appeal, a copy of." Capitalize "The."

R1-6-301(B) and (C)

COMMENT: The order of these 2 subsections should be switched to track the process more sequentially.

EVALUATION: The commentor is correct.

RESPONSE: Change "B" to "C" and "C" to "B."

R1-6-301(E)

COMMENT: An unnecessary "and" appears after "decision."

EVALUATION: Without the "and" the sentence does not make sense.

RESPONSE: No change.

R1-6-401

COMMENT: This rule places new copying burdens on the agencies and the public. The economic, small business, and consumer impact statement needs to address this.

EVALUATION: The commentor is correct that this rule creates a new burden. However, the rules as amended reduce the overall copying burden.

RESPONSE: No rule change, but see the economic, small business, and consumer impact statement.

R1-6-401(A)(1)(e)

COMMENT: The word "significantly" should be inserted between "impact" and "exceeded" to be consistent with A.R.S. § 41-1056.01.

EVALUATION: The commentor is correct.

RESPONSE: Insert "significantly" between "impact" and "exceeded."

R1-6-401(B) and (C)

COMMENT: The order of these 2 subsections should be switched to track the process more sequentially.

EVALUATION: The commentor is correct.

RESPONSE: Change "B" to "C" and "C" to "B."

R1-6-401(D)

COMMENT: This Section discusses the notice to be sent to 2 parties if the Council has 3 members wishing to consider an appeal. Because the agency is waiting to see whether the Council is going to hear the appeal, the Council should write a letter to the agency to acknowledge that they are not going to hear the appeal.

EVALUATION: This subsection requires the Council to send a letter to the agency that notifies the agency whether the Council will hear the appeal.

RESPONSE: No change.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
None.
12. Incorporations by reference and their location in the rules:
None.
13. Was the rule previously adopted as an emergency rule?
No.
14. The full text of the rules follows:

TITLE 1. RULES AND THE RULEMAKING PROCESS

CHAPTER 6. GOVERNOR'S REGULATORY REVIEW COUNCIL

ARTICLE 1. RULES OF PROCEDURE

- R1-6-101. Meetings
- R1-6-102. Schedule and Filing Deadlines
- R1-6-103. Submission of Rules
- R1-6-104. Rules Approved by the Council
- R1-6-105. Returned Rules
- R1-6-107. Oral and Written Comments
- R1-6-108. 5-Year-Review Reports

**ARTICLE 3. AGENCY PRACTICE OR SUBSTANTIVE
POLICY STATEMENTS**

- R1-6-301. Appeals of Existing Agency Practices or Substantive Policy Statements

**ARTICLE 4. APPEALS OF ECONOMIC, SMALL BUSI-
NESS, AND CONSUMER IMPACT STATEMENTS**

- R1-6-401. Appeals of Economic, Small Business, and Con-
sumer Impact Statements

ARTICLE 1. RULES OF PROCEDURE

R1-6-101. Meetings

- A. The Chair, in consultation with the Council, shall set regular meeting dates of the Council for each calendar fiscal year by the preceding October 31 April 30. Notice of a regular meeting shall be posted according to the Open Meeting Law, A.R.S. § 38-431, et. seq. at least 10 calendar days before a regular meeting.
- B. The Council may schedule a special meeting to consider rules resubmitted to the Council; appeals of delegation agreements; appeals of economic, small business, and consumer impact statements, appeals of substantive policy statements; or for other matters. Notice of a special meeting shall be posted according to the Open Meeting Law, A.R.S. § 38-431, et. seq., at least 48 hours before a special meeting.
- C. No change.

R1-6-102. Schedule and Filing Deadlines

The Council shall establish for each calendar fiscal year, by the preceding October 31 April 30, a schedule containing filing deadlines, publication dates, and meeting dates for Council review of:

1. No change.
2. Resubmissions of rules pursuant to R1-6-105(1); and
3. No change.

R1-6-103. Submission of Rules

- A. For each adopted regular rule submission, an agency shall deliver to the Council office the following documents format-
ted as required by the rules of the Secretary of State:
 1. Eleven rule packages that contain the following docu-
ments assembled in the following order: One original and
11 copies of the following:
 - a. Cover A cover letter signed by the agency head

director specifying:

- i. The close of the record date and the date the rules were adopted by the agency;
- ii. The ~~procedures followed for adopting the rule~~ including the dates the following were published in the *Register*:
 - (1) Notice of Docket Opening, as required by A.R.S. § 41-1021(C);
 - (2) Notice of Proposed Rulemaking, as required by A.R.S. § 41-1022; Proposed rule
 - (3) Any supplemental notices, as required by ~~pursuant to~~ A.R.S. § 41-1022(D);
 - (4) Notice of Oral Proceeding, as required by A.R.S. § 41-1023(D) ~~4013(D); and~~
 - (5) ~~Any other notice~~ Notice of public participation as set forth in (See A.R.S. § 41-1023);
- iii. A statement of whether definitions of terms contained in statutes or other rules and used in the adopted rule have been attached;
- iv. If applicable, a statement that the rulemaking relates to a 5-year-review report and the date the report was accepted by the Council; and
- v. ~~iii~~ A list of all documents enclosed;
- b. Notice of Final Rulemaking, required by A.A.C. R1-1-601, including the preamble;
- b. ~~A copy of the existing rule if the rule is not shown as part of the revised text of a rule the agency is amend-
ing;~~
- c. Table of contents for the adopted rule;
- e. ~~Copies of the general and specific statutes authoriz-
ing the agency to adopt the rule;~~
- d. Text of the adopted rule;
- d. ~~Copies of definitions of terms, contained in statutes
or other rules, used in the adopted rule;~~
- e. Economic, small business, and consumer impact
statement that contains the information required by
A.R.S. § 41-1055;
- e. ~~All written comments submitted by the public con-
cerning the rule; and~~
- f. Concise explanatory statement that contains the
information required by A.R.S. § 41-1036;
- f. ~~A summary of the contents of the presentations
made at an oral proceeding or a tape recording of an
oral proceeding if an oral proceeding was held;~~
- g. Copy of the existing rule if the existing rule is not
shown as part of the revised text of a rule the agency
is amending;
- h. Copy of the general and specific statutes authorizing
the rule; and
- i. Copy of definitions of terms, contained in statutes or

Notices of Final Rulemaking

- other rules, used in the adopted rule, if any.
2. One ~~copy of each original and 15 copies~~ of the following:
 - a. ~~All written comments submitted by the public concerning the proposed rule; and~~
 - a. ~~The text of the adopted rule;~~
 - b. ~~Materials incorporated by reference, if any.~~
 - b. ~~A preamble that includes all of the information listed in A.R.S. § 41-1001(14);~~
 - c. ~~A table of contents;~~
 - d. ~~An economic, small business, and consumer impact statement that contains the information required by A.R.S. § 41-1055; and~~
 - e. ~~A concise explanatory statement that contains the information required by A.R.S. § 41-1036.~~

~~3. Two copies of materials incorporated by reference.~~

B. For each adopted regular rule approved by the Council, an agency shall deliver to the Council office within 14 calendar days after Council action, unless otherwise authorized by the Council the following documents formatted as required by the rules of the Secretary of State:

1. A letter identifying each change made at the direction of the Council;
2. One original and 5 copies of the following documents assembled in the following order:
 - a. Agency certificate, required by A.A.C. R1-1-105(B);
 - b. Text of the adopted rule containing the changes required by the Council, if any; and
 - c. Items listed in subsections (A)(1)(b), (A)(1)(c), (A)(1)(e), and (A)(1)(f).
3. One original and 1 copy of the receipt required by A.A.C. R1-1-106.

C.B. For each summary rule, an agency shall deliver to the Council office the following documents formatted as required by the rules of the Secretary of State:

1. For a proposed summary rule, 1 one copy original and 11 copies of the following documents assembled in the following order:
 - a. ~~b.~~ Notice The notice of Proposed Summary Rulemaking proposed summary rule making, including the preamble, filed with the Office of the Secretary of State, required by A.R.S. § 41-1027(B);
 - b. Table of contents for the proposed summary rule;
 - c. ~~a.~~ Text The text of the proposed summary rule; and
 - d. Statute that repeals or supersedes the authority under which the original rule was enacted or the statute that is repeated verbatim in the original rule or proposed summary rule.
2. For an adopted summary rule:
 - a. Eleven rule packages that contain the following documents assembled in the following order One original and 15 copies of the following:
 - i. Notice of Summary Rulemaking, required by A.A.C. R1-1-801, including the preamble;
 - ii. A preamble that includes all the information listed in A.R.S. § 41-1001(14);
 - iii. Table A table of contents for the adopted summary rule;
 - iv. Text The text of the adopted summary rule;
 - v. Economic An economic, small business, and consumer impact statement that contains the information required by A.R.S. § 41-1055; and
 - v. Concise A concise explanatory statement that contains the information required by A.R.S. § 41-1036; and
 - b. One copy original and 11 copies of all written com-

ments submitted by the public concerning the rule.

D. For each adopted summary rule approved by the Council, an agency shall deliver to the Council office within 14 calendar days after Council action, unless otherwise authorized by the Council the following documents formatted as required by the rules of the Secretary of State:

1. A letter identifying each change made at the direction of the Council;
2. One original and 5 copies of the following documents assembled in the following order:
 - a. Agency certificate, required by A.A.C. R1-1-105(B);
 - b. Text of the adopted summary rule containing the changes required by the Council, if any; and
 - c. Items listed in subsections (C)(2)(a)(i), (C)(2)(a)(ii), (C)(2)(a)(iv), and (C)(2)(a)(v).
3. One original and 1 copy of the receipt required by A.A.C. R1-1-106.

E.G. No change.

R1-6-104. Rules Approved by the Council

A. When the Council approves an agency's rules as submitted, the Council shall file the original and ~~4 four~~ copies of the agency certificate; rule; preamble; concise explanatory statement; economic, small business, and consumer impact statement; 2 copies of the agency receipt; and 1 one copy of materials incorporated by reference with the Office of the Secretary of State, ~~or, upon written request from the agency, shall return the documents to the agency in a sealed envelope or container. Whether filing the documents with the Office of the Secretary of State or returning the documents to the agency,~~ the Council shall include a written notice signed by the Chair specifying the Sections approved and the date of Council approval. ~~If the Council returns the documents to the agency, the notice shall state that the envelope or container shall not be unsealed before the documents are filed with the Office of the Secretary of State.~~

B. The Council may vote to approve an adopted rule, preamble, or economic, small business, and consumer impact statement after providing the agency with the exact words of each change to be made.

~~1. The agency shall submit a letter identifying each change made and one original and 4 copies of the revised rule, preamble, or economic, small business, and consumer impact statement to the Chair by 14 calendar days of the Council action unless otherwise authorized by the Council.~~

~~2.1. The Chair shall verify that each change required by the Council was made and file the original and 4 four copies of the agency certificate; rule; ; preamble; ; concise explanatory statement; ; and economic, small business, and consumer impact statement; 2 copies of the agency receipt; and 1 one copy of materials incorporated by reference with the Office of the Secretary of State, or, upon written request from the agency, shall return the documents to the agency in a sealed envelope or container. Whether filing the documents with the Office of the Secretary of State or returning the documents to the agency, the Council shall include a written notice signed by the Chairs specifying the Sections approved and the date of Council approval. If the Council returns the documents to the agency, the notice shall state that the envelope or container shall not be unsealed before the documents are filed with the Office of the Secretary of State.~~

~~3.2. No change.~~

C. No change.

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R1-6-105. Returned Rules

The Council may vote to return a rule, preamble, or economic, small business, and consumer impact statement, pursuant to A.R.S. § 41-1052(B), after identifying issues for further consideration by the agency.

1. The Council may ~~shall~~ schedule a date for resubmission in consultation with the agency representative.
2. No change.
3. No change.
4. No change.

R1-6-107. Oral and Written Comments

- A. A person may submit written comments, pursuant to A.R.S. § 41-1052(E), by sending 1 original and 9 copies of the written comments to the Council office and 1 copy to the affected agency head. Written comments shall be received in the Council office and the office of the agency head at least 6 calendar days before the regular Council meeting at which the rule is scheduled on the agenda.
- B. A person making oral comments at a Council meeting shall submit 1 original and 9 copies of visual aids, if used, to the Council office and 1 copy to the affected agency head. A person making oral comments shall submit visual aids to the Council office and the office of the agency head at least 6 calendar days before the regular Council meeting at which the rule is scheduled on the agenda.
- C. All written and oral comments shall relate to a rule scheduled on the Council meeting agenda, cite the particular provision of A.R.S. § 41-1052(C) that is the basis for the Council's authority to consider each issue addressed, and state specifically how the issue relates to that statutory criterion for Council action. The Chair may limit the time allotted to each speaker and preclude repetitious comments.
- D. The Chair may permit a person to submit written comments within the scope of A.R.S. § 41-1052(C) or visual aids if the person establishes good cause for not complying with the document and time requirements in subsection (A) or (B).

R1-6-108. 5 Five-Year-Review Reports

- A. An agency shall include in its 5-year review report the information required by A.R.S. § 41-1056, separately discussing that information and the following:
 - A. An agency shall deliver to the Council office 1 original and 10 copies of a 5-year-review report required by A.R.S. § 41-1056. Except as indicated in subsection (B), the 5-year-review report shall separately discuss and present the following information in the following order for each rule:
 1. General ~~The general~~ and specific statutes authorizing the rule;
 2. Objective ~~The objective~~ of the rule;
 3. Effectiveness ~~The effectiveness~~ of the rule in achieving that objective;
 4. Consistency of the rule ~~The rule's consistency~~ with state and federal statutes and rules, and a listing of the statutes or rules used in determining the consistency;
 5. Agency enforcement policy ~~The status of enforcement of the rule~~, including whether the rule is currently being enforced and, if so, whether there are any problems with enforcement;
 6. Agency views regarding current wisdom of the rule;
 7. Clarity, conciseness, and understandability of the rule;
 8. Summary ~~A summary~~ of the written criticisms of the rule received by the agency within the 5 five years immediately preceding the 5 five-year-review report, including letters, memoranda, and written allegations made in litigation and administrative proceedings in which the agency was a party that the rule is discriminatory, unfair,

unclear, inconsistent with statute ~~statutes~~, or beyond the authority of the agency to enact, and the conclusion of the litigation and administrative proceedings; ~~and~~

9. Estimated economic, small business, and consumer impact of the rule as compared to the economic, small business, and consumer impact statement prepared on the last adoption of the rule; and
10. ~~7. Course~~ The course of action the agency proposes to take regarding each rule, including the month and year in which the agency anticipates opening a rulemaking docket and submitting the rules to the Council ~~will submit the rules to the Council~~ if the agency determines it is necessary to amend, repeal, or adopt a rule.
- B. When the information regarding any of the items listed in subsection (A) is identical for any group of rules, the agency shall discuss that information in its 5-year-review report only once for the group of rules.
- B. An agency shall submit a single, combined 5-year-review report for any group of rules for which the information regarding any of the issues listed in subsection (A) is identical.
- C. The 5-year-review report shall have attached the following: An agency shall deliver 1 original and 11 copies of its 5-year-review report to the Council office.
 1. Copy of the rules being reviewed, and
 2. Copy of the general and specific authorizing statutes.

ARTICLE 3. AGENCY PRACTICE OR SUBSTANTIVE POLICY STATEMENTS

R1-6-301. Appeals of Existing Agency Practices or Substantive Policy Statements

- A. A person appealing an agency's final decision regarding a petition for review of an existing agency practice or substantive policy statement filed pursuant to A.R.S. § 41-1033(B) shall deliver to the Council office 1 original and 9 copies of the following:
 1. A written request signed by the person submitting the appeal that sets forth the following:
 - a. Name of the agency upon which the appeal is taken;
 - b. Name, address, and facsimile and telephone numbers of the person filing the appeal;
 - c. Name of the entity or person being represented by the person filing the appeal;
 - d. Subject matter of the existing agency practice or substantive policy statement being appealed; and
 - e. Reasons why the person appealing believes that the existing agency practice or substantive policy statement constitutes a rule; and
 2. The petition requesting a review of the agency's existing practice or substantive policy statement.
 3. The agency's written decision to each petition submitted to the agency requesting a review of the agency's existing practice or substantive policy statement being appealed.
- B. The Council shall notify the affected agency head of an appeal of an existing agency practice or a substantive policy statement by 5 p.m. of the business day following Council receipt of the appeal. The agency shall deliver to the Council office the information and documents set forth in subsection (C) no later than 5 p.m. on the 3rd business day following notification by the Council of the appeal.
- C. An agency whose final decision is being appealed shall deliver to the Council office 1 original and 9 copies of the following:
 1. A memorandum that sets forth the following:
 - a. Date the agency gave written notice of its decision pursuant to A.R.S. § 41-1033(A);
 - b. Name, address, and facsimile and telephone numbers of each agency contact person; and

- c. Reasons why the agency believes that the existing agency practice or substantive policy statement does not constitute a rule;
- 2. The existing agency practice or substantive policy statement being appealed;
- 3. Each petition filed with the agency requesting a review of the agency's existing practice or substantive policy statement being appealed; and
- 4. The agency's written decision to each petition submitted to the agency requesting a review of the agency's existing practice or substantive policy statement being appealed.
- D. Within 14 calendar days after an appeal is filed with the Council, the Chair shall send written notice to the person filing the appeal and the affected agency head stating whether 3 Council members have requested that the appeal be considered at a Council meeting. If the appeal is to be considered at a Council meeting, the notice shall include the date and time of the Council meeting.
- E. Within 7 calendar days after the Council decides whether the agency practice or substantive policy statement constitutes a rule, the Chair shall send a letter to the affected agency and the person filing the appeal that specifies the decision and the reasons for and date of the Council decision.

ARTICLE 4. APPEALS OF ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENTS

R1-6-401. Appeals of Economic, Small Business, and Consumer Impact Statements

- A. A person appealing an agency's final decision on whether to initiate a rulemaking pursuant to A.R.S. § 41-1056.01(D), shall deliver to the Council office 1 original and 9 copies of the following:
 - 1. The written request signed by the person submitting the appeal, citing the rule or rules being appealed and setting forth the following:
 - a. Name of the agency upon which the appeal is taken;
 - b. Name, address, and facsimile and telephone numbers of the person filing the appeal;
 - c. Name of the entity or person being represented by the person filing the appeal;
 - d. Manner in which the person filing the appeal is or may be affected by the agency's final decision made pursuant to A.R.S. § 41-1056.01(C); and
 - e. Reasons why the person appealing believes either that the actual economic, small business, or consumer impact significantly exceeded the estimated impact pursuant to A.R.S. § 41-1056.01(A)(1), or that the actual economic, small business, or consumer impact was not estimated on adoption of the rule and that the impact imposes a significant burden on persons subject to the rule pursuant to A.R.S. §

- 41-1056.01(A)(2);
- 2. The economic, small business, and consumer impact statement being addressed in the appeal; and
- 3. The data used by the person appealing to support the reasons set forth under subsection (A)(1)(e).
- B. The Council shall notify the affected agency head of an appeal of a rule and its impact by 5 p.m. of the business day following Council receipt of the appeal. The agency shall deliver to the Council office the information and documents set forth in subsection (C) no later than 5 p.m. on the 3rd business day following notification by the Council of the appeal.
- C. An agency whose final decision is being appealed shall deliver to the Council office 1 original and 9 copies of the following:
 - 1. A memorandum that sets forth the following:
 - a. Date of the publication of the agency's final decision pursuant to A.R.S. § 41-1056.01(C);
 - b. Name, address, and facsimile and telephone numbers of each agency contact person;
 - c. If appropriate, reasons why the agency believes either that the actual economic, small business, and consumer impact did not significantly exceed the estimated economic, small business, and consumer impact or that the actual economic, small business, and consumer impact was estimated on adoption of the rule and that the impact does not impose a significant burden on persons subject to the rule, or both; and
 - d. Final judgments, if any, issued by a court of competent jurisdiction that are based on whether the contents of the adopted rule's economic, small business, and consumer impact statement were insufficient or inaccurate;
 - 2. The rule being appealed; and
 - 3. The agency's written summary of comments received about the rule and its impact, the agency's response to those comments, and the agency's final decision on whether to adopt, amend, or repeal the rule.
- D. Within 14 calendar days after an appeal is filed with the Council, the Chair shall send written notice to the person filing the appeal and the affected agency head stating whether 3 Council members have requested that the appeal be considered at a Council meeting. If the appeal is to be considered at a Council meeting, the notice shall include the date and time of the Council meeting.
- E. Within 7 calendar days after the Council decides whether either or both of the provisions set forth in A.R.S. § 41-1056.01(A) are met, the Chair shall send a letter to the affected agency and the person filing the appeal that specifies the decision, the reasons for and date of the Council decision, and the action, if any, required by the agency.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. **Sections Affected**

R4-23-110 R4-23-606 R4-23-612 R4-23-651 R4-23-671 R4-23-672 R4-23-673	<u>Rulemaking Action</u> Amend Amend Amend Amend New Section New Section New Section
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2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. § 32-1904(A)(1) and (2) and (B)(3), (4), and (6).
Implementing statutes: A.R.S. §§ 32-1929, 32-1930(A)(2), (B), and (C) and 32-1931.
3. **The effective date of the rules:**

April 5, 1996
4. **A list of all previous notices appearing in the Register addressing the final rule:**

Notice of Rulemaking Docket Opening:
1 A.A.R. 200, March 17, 1995

Notice of Proposed Rulemaking:
1 A.A.R. 1218, July 28, 1995

Notice of Terminated Rulemaking:
1 A.A.R. 1931, October 20, 1995

Notice of Rulemaking Docket Opening:
1 A.A.R. 1939, October 20, 1995

Notice of Proposed Rulemaking:
1 A.A.R. 1908, October 20, 1995

Notice of Supplemental Proposed Rulemaking:
1 A.A.R. 2277, November 3, 1995
5. **The name and address of agency personnel with whom persons may communicate regarding the rule:**

Name: Address: Telephone: Fax:	Dean Wright, Compliance Officer Board of Pharmacy 5060 North 19th Ave., Suite 101 Phoenix, Arizona 85015 (602) 255-5125, ext. 131 (602) 255-5740
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6. **An explanation of the rule, including the agency's reasons for initiating the rule:**

The practice of pharmacy is changing rapidly and a big part of this change is specialization. Pharmacies can no longer be viewed as just community or hospital. To protect the citizens of Arizona, the Board proposes to change the rules to define and control better today's pharmacy practice. R4-23-110 is amended to define Correctional facility, Limited-service correctional and Mail-order pharmacy, Limited-service pharmacy permittee, and Remote drug storage area. The heading of R4-23-606 is amended to include Limited-service Pharmacy. R4-23-612 is amended to update the requirement of a professional reference library. Instead of 2 current references from a limited list, each pharmacy would need a minimum of 1 current reference addressing 4 pharmacy topics. R4-23-651 is amended to define more concisely hospital pharmacy and to delete the definition of Hospital because it is defined in statute, A.R.S. § 32-1901. R4-23-671 is a new Section providing general requirements for limited-service pharmacies. R4-23-672 is a new Section providing rules governing pharmacies in correctional facilities. Presently, correctional pharmacies are classified as community pharmacies. The practice of pharmacy in a correctional facility more closely resembles a hospital than a community pharmacy. These rules use the limited-service pharmacy permit to address the scope of pharmacy practice inside the closed and very tightly controlled system of a correctional facility. The new class of pharmacy will give the Board satisfactory guidelines to monitor the practice of correctional pharmacy and protect the health and welfare of the correctional facility population. The rule is specific for the type of practice and utilizes a Board approved policy and procedure manual to regulate a particular pharmacy bet-

Notices of Final Rulemaking

ter. R4-23-673 is a new Section providing rules governing mail-order pharmacies. Mail-order pharmacies have always been classified as community pharmacies. These rules use the limited-service pharmacy permit to address the scope of practice in this rapidly growing area of pharmacy. Mail-order pharmacies are ahead of most pharmacies in their innovative use of technology and personnel. The rule establishes a new class of pharmacy with rules specific for the type of practice and utilizes a Board-approved policy and procedure manual to regulate a particular pharmacy better.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards governing pharmacy practice in specialized settings. The Board further believes that specific regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists in a dynamic health care system.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

8. The summary of the economic, small business, and consumer impact:

The principal impact of the rule will be on pharmacies and pharmacists. For pharmacists, the rule will place additional responsibility on them for writing and reviewing a policy and procedure manual. The benefit for pharmacists will be better control of all aspects of their pharmacy practices through written policies and procedures.

For pharmacies, the rule will establish concise and specific regulation and control over individual areas of limited pharmacy service. These specialized pharmacies will be able to practice within a set of rules that provide protection of public health and safety and allow service by a unique method or to a particular population. Because the fees are the same for community, hospital or limited-service pharmacy, the rule will have minimal economic impact for most pharmacies. The rule requires mail-order pharmacies to provide toll-free telephone service for a minimum of 40 hours per week. However, this will have little real impact, because all mail-order pharmacies in Arizona already provide toll-free telephone service. Because all pharmacies are presently required to have 2 current references, the proposed rule will have little or no economic effect.

There is no expected economic impact on consumers or small business by these rules.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no changes in the final rules since the publication of the notices of proposed rulemaking and supplemental proposed rulemaking.

10. A summary of the principal comments and the agency response to them:

No comments were received.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their location in the rules:

None.

13. Was this rule previously adopted as an emergency rule?

No.

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-606. Pharmacy Permit, Community, and Hospital, and Limited Service
R4-23-612. Equipment
R4-23-651. Definitions
R4-23-671. General Requirements for Limited-service Pharmacy
R4-23-672. Limited-service Correctional Pharmacy
R4-23-673. Limited-service Mail-order Pharmacy

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to the definitions set forth in A.R.S. § 32-1901, the fol-

lowing definitions apply to this Chapter.

- ~~A.~~ No change.
- ~~B.~~ No change.
- ~~C.~~ No change.
- ~~D.~~ No change.
- ~~E.~~ No change.
- ~~F.~~ No change.
- ~~G.~~ No change.
- ~~H.~~ No change.
- ~~I.~~ "Correctional facility" has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.
- ~~J.~~ "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.
- ~~K.~~ No change.
- ~~L.~~ No change.
- ~~M.~~ No change.
- ~~N.~~ No change.
- ~~O.~~ No change.
- ~~P.~~ "Limited-service correctional pharmacy" means a limited-ser-

Notices of Final Rulemaking

vice pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding, production, dispensing, and distribution of drugs.

Q: "Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and dispenses a majority of its prescription medications or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

R: "Limited-service pharmacy permittee" means a person who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

S: "Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

P-T: No change.

Q-U: No change.

R-V: No change.

S-W: No change.

T-X: No change.

U-Y: No change.

V-Z: No change.

W-AA: No change.

X-BB: No change.

Y-CC: No change.

Z-DD: No change.

AA-EE: No change.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

BB-FF: No change.

CC-GG: No change.

DD-HH: No change.

EE-IJ: No change.

FF-JJ: No change.

GG-KK: No change.

HH-LL: No change.

HM-MM: No change.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-606. Pharmacy Permit, Community, and Hospital, and Limited Service.

A. No change.

B. No change.

C. No change.

D. No change.

E. No change.

F. No change.

G. No change.

H. No change.

I. No change.

J. No change.

K. No change.

L. No change.

1. No change.

a. No change.

b. No change.

c. No change.

d. No change.

e. No change.

2. No change.

3. No change.

4. No change.

5. No change.

a. No change.

b. No change.

c. No change.

d. No change.

e. No change.

6. No change.

R4-23-612. Equipment

Each pharmacy shall contain the following:

1. No change.

2. No change.

3. No change.

4. No change.

5. No change.

6. No change.

7. No change.

8. No change.

9. No change.

10. No change.

11. No change.

12. ~~Any 2 of the following references, which shall be kept current:~~

~~a. United States Pharmacopeia and National Formulary.~~

~~b. United States Pharmacopeia Dispensing Information.~~

~~c. American Hospital Formulary Service.~~

~~d. Facts and Comparisons.~~

~~e. O.T.C. Handbook.~~

~~f. Remington's Pharmaceutical Sciences.~~

A professional reference library consisting of a minimum of 1 current reference or text addressing the following subject areas:

a. Pharmacology or toxicology.

b. Therapeutics.

c. Drug compatibility, and

d. Drug product equivalency.

13. No change.

14. No change.

15. No change.

16. No change.

R4-23-651. Definitions

~~For the purposes of these rules, the~~ The following definitions apply to R4-23-651 through R4-23-659:

~~1.~~ No change.

~~2.~~ No change.

~~3.~~ No change.

~~4.~~ No change.

~~5.~~ No change.

~~6.~~ No change.

~~7. "Hospital" means any institution for the care and treatment of the sick and injured which is approved and licensed as a hospital by the state Department of Health Services.~~

8. "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, sale, and distribution of drugs used in the diagnosis and treatment of injury, illness, and disease and which is permitted by the state Board of Pharmacy pursuant to A.R.S. § 32-1931 and as defined in A.R.S. § 32-1901 a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and is located in a hospital, as defined in A.R.S. § 32-1901.

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- 9- No change.
- 10- No change.
- 11- No change.
- 12- No change.
- 13- No change.
- 14- No change.
- 15- No change.
- 16- No change.
- 17- No change.
- 18- No change.

R4-23-671. General Requirements for Limited-service Pharmacy

- A. Before opening a limited-service pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
- B. The limited-service pharmacy permittee shall secure the limited-service pharmacy by conforming with the following standards:
 - 1. Permit no one to be in the limited-service pharmacy unless a pharmacist authorized by the pharmacist-in-charge pursuant to R4-23-672(B) or R4-23-673(E) is present;
 - 2. Require the pharmacist-in-charge to designate in writing, by name, title, and specific area, those persons who will have access to particular areas of the limited-service pharmacy;
 - 3. Implement procedures to guard against theft or diversion of drugs, including controlled substances; and
 - 4. Require all persons working in the limited-service pharmacy to wear badges, with their names and titles, while on duty.
- C. To obtain permission to deviate from the minimum area requirement set forth in R4-23-609 or R4-23-673, a limited-service pharmacy permittee shall submit a written request to the Board and include documentation that the deviation will facilitate experimentation or technological advances in the practice of pharmacy as defined in A.R.S. § 32-1901. If the Board determines the requested deviation from the minimum area requirement will enhance the practice of pharmacy and benefit the public, the Board shall grant the requested deviation.
- D. The Board shall require more than the minimum area in a limited-service pharmacy when the Board determines that equipment, personnel, or other factors in the limited-service pharmacy cause crowding that interferes with safe pharmacy practice.
- E. Before dispensing from a limited-service pharmacy, the pharmacist-in-charge shall:
 - 1. Prepare written policies and procedures for pharmacy operations and drug distribution.
 - 2. Submit a copy of the written policies and procedures to the Board office with the original permit application.
 - 3. Conduct a biennial review and revision of the policies and procedures and submit a copy of any revision to the Board office, and
 - 4. Make the policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.

R4-23-672. Limited-service Correctional Pharmacy

- A. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy complies with the standards for area, personnel, security, sanitation, equipment, drug distribution and control, administration of drugs, drug source, quality assurance, investigational drugs, and inspections as set forth in R4-23-608, R4-23-609(A) through (D) and (F)

through (H), R4-23-610(A), R4-23-611, R4-23-612, R4-23-653(D), except (2)(e), R4-23-658(B) through (H) and R4-23-660 through R4-23-664.

- B. The pharmacist-in-charge of a limited-service correctional pharmacy shall authorize only pharmacists, interns, drug inspectors, peace officers, and correctional officers acting in their official capacities, supportive personnel, and other designated personnel to be in the limited-service correctional pharmacy.
- C. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have access to drugs in remote drug storage areas or, if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient, in the limited-service correctional pharmacy.
 - 1. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that remote drug storage areas:
 - a. Contain only properly labeled drugs that might reasonably be needed and can be administered safely during the absence of a pharmacist.
 - b. Contain drugs packaged only in amounts sufficient for immediate therapeutic requirements.
 - c. Are accessible only with a physician's written order.
 - d. Provide a written record of each drug withdrawn.
 - e. Are inventoried at least once each week, and
 - f. Are audited for compliance with the requirements of this rule at least once each month.
 - 2. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that access to the limited-service correctional pharmacy when no pharmacist is on duty conforms to the following requirements:
 - a. Is delegated to only 1 nurse, who is in a supervisory position;
 - b. Is communicated in writing to medical staff of the correctional facility;
 - c. Is delegated only to a nurse who has received training from the pharmacist-in-charge in proper methods of access, removal of drugs, and records and procedures required; and
 - d. Is delegated by the supervisory nurse to another nurse only in emergencies.
 - 3. When a nurse to whom authority to access the limited-service correctional pharmacy is delegated removes a drug from the limited-service correctional pharmacy, the nurse shall:
 - a. Record the following information on a form:
 - i. Patient's name,
 - ii. Name of the drug and its strength and dosage form,
 - iii. Dose prescribed,
 - iv. Amount of drug removed, and
 - v. Date and time of removal;
 - b. Sign the form recording the drug removal;
 - c. Attach the original or a direct copy of a physician's written order for the drug to the form recording the drug removal; and
 - d. Place the form recording the drug removal conspicuously in the limited-service correctional pharmacy.
 - 4. Within 4 hours after a pharmacist in the limited-service correctional pharmacy returns to duty following an

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absence in which the limited-service correctional pharmacy was accessed by a nurse to whom authority had been delegated, the pharmacist shall verify all records of drug removal in accordance with R4-23-402.

D. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have telephone access to a pharmacist.

E. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy is without a pharmacist on duty for no more than 96 consecutive hours.

F. In addition to the requirements of R4-23-671, the limited-service pharmacy permittee shall secure the limited-service correctional pharmacy by conforming with the following standards:

1. Permit no one to be in the limited-service correctional pharmacy unless a pharmacist is on duty except:

a. As provided in subsection (C)(3) when no pharmacist is on duty; or

b. Pharmacy technicians may remain to perform duties outlined in R4-23-653(D)(2), except subsection (D)(2)(e), when a pharmacist is on duty and available in the correctional facility but temporarily absent from the pharmacy, provided all controlled substances are secured in a manner that prohibits access by persons other than a pharmacist; and

2. Provide keyed or programmable locks to all areas of the limited-service correctional pharmacy.

G. The pharmacist-in-charge of a limited-service correctional pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution within the correctional facility include the following:

1. Physicians' orders, prescription orders, or both;

2. Authorized abbreviations;

3. Formulary system;

4. Clinical services and drug utilization management including:

a. Participation in drug selection,

b. Drug utilization reviews,

c. Inventory audits,

d. Patient outcome monitoring,

e. Committee participation,

f. Drug information, and

g. Education of pharmacy and other health professionals;

5. Duties and qualifications of professional and support staff;

6. Products of abuse and contraband medications;

7. Controlled substances;

8. Drug administration;

9. Drug product procurement;

10. Drug compounding, dispensing, and storage;

11. Stop orders;

12. Pass/Discharge medications;

13. Investigational drugs and their protocols;

14. Patient profiles;

15. Quality management procedures for:

a. Adverse drug reactions;

b. Drug recalls;

c. Expired and beyond-use-date drugs;

d. Medication or dispensing errors;

e. Drug storage; and

f. Education of professional staff, support staff, and patients;

16. Recordkeeping;

17. Sanitation;

18. Security;

19. Access to remote drug storage areas by non-pharmacists; and

20. Access to limited-service correctional pharmacy by non-pharmacists.

R4-23-673. Limited-service Mail-order Pharmacy

A. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:

1. A dispensing area devoted to stocking, compounding, and dispensing prescription medications, which is physically separate from a non-dispensing area devoted to non-dispensing pharmacy services;

2. A dispensing area of at least 300 square feet if 3 or fewer persons work in the dispensing area simultaneously;

3. A dispensing area that provides 300 square feet plus 60 square feet for each person in excess of 3 persons if more than 3 persons work in the dispensing area simultaneously;

4. Space in the dispensing area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist;

5. A non-dispensing area of at least 30 square feet for each person working simultaneously in the non-dispensing area; and

6. Space in the non-dispensing area permits free movement of personnel and visual surveillance by the pharmacist; or

B. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:

1. A contiguous area in which both dispensing and non-dispensing pharmacy services are provided;

2. A contiguous area of at least 300 square feet if 3 or fewer persons work in the area simultaneously;

3. A contiguous area that provides 300 square feet plus 60 square feet for each person in excess of 3 persons if more than 3 persons work in the area simultaneously; and

4. Space in the contiguous area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist.

C. The limited-service pharmacy permittee shall allow no more than 4 supportive personnel per pharmacist to be in the limited-service mail-order pharmacy.

D. The limited-service pharmacy permittee shall ensure that the limited-service mail-order pharmacy complies with the standards for area, personnel, security, sanitation, and equipment set forth in R4-23-608, R4-23-609(B) through (H), R4-23-610 (A) and (C) through (F), R4-23-611(A) through (I), and R4-23-612.

E. The pharmacist-in-charge of a limited-service mail-order pharmacy shall authorize only pharmacists, interns, drug inspectors, peace officers acting in their official capacities, supportive personnel, and other designated personnel to be in the limited-service mail-order pharmacy.

F. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that prescription medication is delivered to the patient or locked in the dispensing area when a pharmacist is not present in the pharmacy.

G. In addition to the delivery requirements of R4-23-402, the limited-service pharmacy permittee shall, during regular hours of operation but not less than 6 days and a minimum 40 hours per week, provide toll-free telephone service to facilitate communication between patients and a pharmacist who has access to patient records at the limited-service mail-order pharmacy. The limited-service pharmacy permittee shall disclose this

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toll-free number on a label affixed to each container of drugs dispensed from the limited-service mail-order pharmacy.

H. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution include the following:

1. Prescription orders;
2. Clinical services and drug utilization management for:
 - a. Drug utilization reviews,
 - b. Inventory audits,
 - c. Patient outcome monitoring,
 - d. Drug information, and
 - e. Education of pharmacy and other health professionals;
3. Duties and qualifications of professional and support staff;
4. Controlled substances;
5. Drug product procurement;

6. Drug compounding, dispensing, and storage;
7. Patient profiles;
8. Quality management procedures for:
 - a. Adverse drug reactions,
 - b. Drug recalls,
 - c. Expired and beyond-use-date drugs,
 - d. Medication or dispensing errors, and
 - e. Education of professional and support staff;
9. Recordkeeping;
10. Sanitation;
11. Security;
12. Drug delivery requirements for:
 - a. Transportation,
 - b. Security,
 - c. Temperature and other environmental controls,
 - d. Emergency provisions, and
13. Patient education.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 1. DEPARTMENT OF HEALTH SERVICES

ADMINISTRATION

PREAMBLE

1. Sections Affected
R9-1-412
- Rulemaking Action
Amend
2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. § 36-136(F)
Implementing statute: A.R.S. § 36-405(A)
3. The effective date of the rules:
April 3, 1996
4. A list of all previous notices appearing in the Register addressing the final rule:
Notice of Rulemaking Docket Opening:
1 A.A.R. 461, May 12, 1995
Notice of Proposed Rulemaking:
2 A.A.R. 7, January 5, 1996
5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
Name: Tom Thliveris
Address: Department of Health Services
1647 East Morten, Suite 180
Phoenix, Arizona 85020
Telephone: (602) 255-1144
Fax: (602) 255-1109
6. An explanation of the rule, including the agency's reasons for initiating the rule:
R9-1-412 lists the physical plant health and safety codes and standards that the Department uses when reviewing physical plant requirements of health care institutions or child care facilities that are seeking licensure by the Department. Food service or food establishments are also required to comply with the applicable physical plant health and safety codes and standards referenced in R9-1-412. The Department refers to the codes and standards referenced in R9-1-412 throughout Title 9. The Department is updating the referenced codes and standards in R9-1-412.
7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:
Not applicable.

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8. The summary of the economic, small business, and consumer impact:

The overall economic impact of the rule is that the benefits outweigh the costs. Health care institutions and child care facilities stand to benefit economically through the Department's adoption of newer codes and standards particularly when construction or modification of health care institutions or child care facilities are involved. The newer codes and standards provide more safety measures, greater flexibility, and reliability for health care institutions and child care facilities. For example, the adopted 1992-93 edition of Guidelines for Construction and Equipment of Hospital and Medical Facilities is more effective in promoting quality health care as well as being cost effective for health care institutions. Additionally, over 120 pending child care facilities will benefit economically from the Department's adoption of newer codes and standards because these facilities will be able to construct fire-resistive facilities with less building costs while still meeting the minimum health and safety standards. The pending construction/equipment of over 70 medical facilities that represent hospitals, skilled nursing institutions, and outpatient surgical facilities will be positively impacted because design consultants and contractors can present plans in conformance with the newly adopted codes and standards.

Health care institutions that meet the definition of small businesses will not be adversely affected by the adoption of these rules.

Consumers will indirectly benefit from safer construction requirements of health care institutions.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The phrase "Volumes 1 through 3" was added to R9-1-412(A)(1). In R9-1-412(A)(2), the following was stricken: "and the International Association of Plumbing and Mechanical Officials, 20001 South Walnut Drive, Walnut, CA 91789-2825". The Department eliminated the Life Safety Code (formerly R9-1-412(B)) and the National Electrical Code (formerly R9-1-412(E)) because those code provisions are contained in the 1995 National Fire Codes which are incorporated at R9-1-412(A)(5). In addition, the volumes for the National Fire Codes were changed from 11 to 12 and the language referencing the supplement to the National Fire Codes was changed to "1995 Supplement, Part 1 and Part 2". In R9-1-412(A)(6), the name of the code, publisher, and address was changed to American National Standard Accessible and Usable Buildings and Facilities, Council of American Building Officials, 5203 Leesburg Pike, #708, Falls Church, VA 22041. In R9-1-412(A)(7), the phrase "Volumes 1 and 2" was added; the publisher's address was changed to 9300 Jollyville Road, Suite 105, Austin, TX 78759-7455; and the phrase, "under the joint sponsorship of the International Conference of Building Officials, Western Fire Chiefs Association, and International Association of Fire Chiefs" was stricken.

Other minor editing, grammatical, and punctuation changes were made but no substantive changes were made between the proposed and final rule.

10. A summary of the principal comments and the agency response to them:

No comments were received.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None.

12. Incorporations by reference and their location in the rules:

Uniform Building Code, Volumes 1 through 3, 1994 editions, incorporated at R9-1-412(1)

Uniform Mechanical Code, 1994 edition, incorporated at R9-1-412(A)(2)

Uniform Plumbing Code, 1994 edition, incorporated at R9-1-412(A)(3)

Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1992-93 edition, incorporated at R9-1-412(A)(4)

National Fire Codes, Volumes 1 through 12, 1995 editions, and 1995 Supplement, incorporated at R9-1-412(A)(5)

American National Standard Accessible and Usable Buildings and Facilities, ANSI A117.1, 1992 edition, incorporated at R9-1-412(A)(6)

Uniform Fire Code, Volumes 1 and 2, 1994 editions, incorporated at R9-1-412(A)(7)

13. Was this rule previously adopted as an emergency rule?:

No.

14. The full text of the rule follows:

TITLE 9. HEALTH SERVICES

CHAPTER 1. DEPARTMENT OF HEALTH SERVICES

ADMINISTRATION

ARTICLE 4. CODES AND STANDARDS REFERENCED

Section

R9-1-412. Physical Plant Health and Safety Codes and Standards

ARTICLE 4. CODES AND STANDARDS REFERENCED

R9-1-412. Physical Plant Health and Safety Codes and Standards

A. When this Section is referenced in a rule contained in Title 9,

the following physical plant health and safety codes and standards, incorporated by reference and on file with the Department and the Office of the Secretary of State, and no future amendments or editions shall apply:

A.1. Uniform Building Code - 1994 edition, Volumes 1 through 3; published by the International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, California 90601-2258/2298. (Formerly R9-1-412(A))

B. Life Safety Code - 1991, NFPA 101; published by the

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~~National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101.~~

~~G.2. Uniform Mechanical Code - 1994/1994 edition; published by the International Conference of Building Officials; 5360 South Workman Mill Road, Whittier, California 90601-2258/2298, and the International Association of Plumbing and Mechanical Officials, 20001 South Walnut Drive, Walnut, CA 91789-2825. (Formerly R9-1-412(C))~~

~~D.3. Uniform Plumbing Code - 1994/1994 edition; published by the International Association of Plumbing and Mechanical Officials, 20001 South Walnut Drive South, Walnut, CA 91789-2825. (Formerly R9-1-412(D))~~

~~E. National Electrical Code - 1993 edition, NFPA 70; published by the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101.~~

~~F.4. Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1987 1992-93 Edition edition; published by the The American Institute of Architects Press, 1735 New York Avenue, N.W., Washington, D.C. 20006. (Formerly R9-1-412(F))~~

~~G.5. National Fire Codes - 1992/1995 editions, Volumes 1 through 11/12, and 1995 Supplement Part 1 and Part 2, published by the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101. (Formerly R9-1-412(G) and includes the former R9-1-412(B). Life Safety Code, NFPA 101 and the former R9-1-412(E).~~

National Electrical Code, NFPA 70)

~~H.6. American National Standard for Buildings and Facilities Providing Accessibility and Usability for Physically Handicapped People Accessible and Usable Buildings and Facilities, ANSI A117.1 - 1986/1992 edition; published by American National Standards Institute, 11 West 42nd Street, New York, NY 10036 Council of American Building Officials, 5203 Leesburg Pike, #708, Falls Church, VA 22041. (Formerly R9-1-412(H))~~

~~I.7. Uniform Fire Code - 1994/1994 Edition edition, Volumes 1 and 2; published by the International Fire Code Institute, 5360 South Workman Mill Road, Whittier, CA 90601-2258 under the joint sponsorship of the International Conference of Building Officials, Western Fire Chiefs Association, and International Association of Fire Chiefs 9300 Jollyville Road, Suite 105, Austin, TX 78759-7455. (Formerly R9-1-412(I)).~~

~~J. Uniform Building Code Standards - 1991 Edition; published by the International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, CA 90601-2258.~~

~~K. The above listed codes and standards are incorporated herein by reference and are on file with the Office of the Secretary of State.~~

~~B. A person shall not be subject to any penalty or fee specified in the physical plant health and safety codes and standards that are incorporated by reference in this Section.~~